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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,771	09/26/2003	Richard David Guarino	P-5840P1	4333
32330	7590	05/05/2005	EXAMINER	
VENABLE LLP 575 7TH STREET, N.W. WASHINGTON, DC 20004-1600			TSAY, MARSHA M	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/670,771

Applicant(s)

GUARINO ET AL.

Examiner

Marsha M. Tsay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-66 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-22, 41-64, drawn to a CAP peptide-modified polymer composition, classified in class 514, subclass 12.
- II. Claim 23-25, drawn to a cell culture system comprising a peptide-modified polymer composition, classified in class 435, subclass 325.
- III. Claims 26-28, drawn to a method for producing a peptide-modified polymer composition, classified in class 530, subclass 334.
- IV. Claim 29, drawn to a method for attaching cells on a cell adhesion resistant (CAR) polymer surface, classified in class 435, subclass 325.
- V. Claims 30-31, 38, 65-66, drawn to a method for growing adherent cells on a cell adhesion resistant (CAR) polymer surface, classified in class 435, subclass 325.
- VI. Claims 32-37, 39-40, drawn to a method of screening a peptide for the ability to promote cell attachment and/or growth to a cell adhesion resistant (CAR) surface, classified in class 435, subclass 7.1.

As defined on page 4, paragraph 3, of the specification: a cell adhesion promoting (CAP) peptide-modified polymer composition promotes attachment, growth,

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differentiation and further function of cells on a polymer surface that is otherwise cell adhesion resistant (CAR). The composition comprises a polymer with a CAR surface to which are bonded one or more of the peptides noted above either alone or in combination. Therefore, this definition is being placed into claim 1.

However, SEQ ID NOs.1-16 are structurally different and therefore have different specific functions, even though they are adhesion promoting. The SEQ ID NOs.1-16 and combinations, thereof, represent an improper Markush group.

Applicants will choose any one of, or any combination of, SEQ ID NOs.1-16 that represent a single cell adhesion promoting peptide-modified polymer composition. It will be understood that all sequence(s) chosen by Applicants will be found within a single polypeptide. This is not a species election, but an election of patentably distinct polypeptides.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a cell adhesion promoting peptide-modified polymer composition and a cell culture system. The two inventions are different products and therefore patentably distinct.

Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

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process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, peptides can be grafted to the surface of a polymer by reacting the terminal primary amine of the polypeptide to an active group on the polymer surface (Hubbell et al. US 5278063), therefore making a cell adhesion promoting peptide-modified polymer composition.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cell adhesion promoting peptide-modified polymer composition can be used as a component in a cell culture system to promote cell growth. This process of use is distinct from Invention III because the utility of Invention III is drawn to cell adherence, not cell growth.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a cell adhesion promoting peptide-modified polymer composition and a method for growing adherent cells on a cell adhesion resistant (CAR) polymer surface.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

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process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cell adhesion promoting peptide-modified polymer composition can be used as a component in a cell culture system to promote cell growth. This process of use is distinct from Invention V because it comprises different method steps.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a cell culture comprising a cell adhesion promoting peptide-modified polymer composition and a method for producing a cell adhesion promoting peptide-modified polymer composition.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a cell culture comprising a cell adhesion promoting peptide-modified polymer composition and a method for attaching cells to a peptide-modified CAR polymer surface using a cell adhesion promoting peptide-modified polymer composition.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

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the instant case the different inventions are a cell culture comprising a cell adhesion promoting peptide-modified polymer composition and a method for growing adherent cells on a cell adhesion resistant (CAR) polymer surface.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a cell culture system comprising a cell adhesion promoting peptide-modified polymer composition and a method of screening a test peptide for the ability to promote cell attachment when covalently bonded to a CAR surface.

Inventions III and IV-VI are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Inventions IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different methods of using a CAP peptide-modified polymer composition. Inventions IV-VI comprise different method steps and are therefore patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

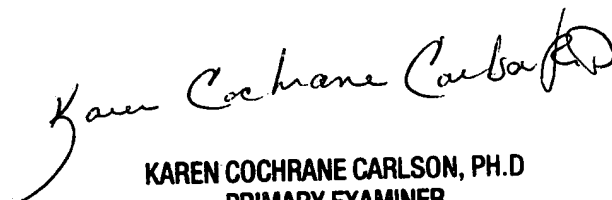
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 29, 2005


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER